DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 14 1997

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Stuart M. Pape
Patton Boggs, L.L.P.
2550 M Street, N.W.
Washington D.C. 20037

Re: Pharmanex, Inc., Petition for Administrative Stay of Action, Docket No. 97P-0441

Dear Mr. Pape,

This letter replies to the Petition for Stay of Action you filed with the Food and Drug Administration (FDA) October 29, 1997, on behalf of your client Pharmanex, Inc. (the Petition). In the Petition, you ask FDA to stay the September 30, 1997, letter sent you by Ilisa Bernstein of FDA, and to stay any form of enforcement action adverse to Pharmanex or its product Cholestin. As explained below, the agency is not acting on the Petition because it has taken no administrative action that can be stayed at this time.

Under FDA's regulations, an interested person may request a stay of the effective date of any "administrative action." 21 C.F.R. § 10.35(b). The term "administrative action" refers to acts (or failures or refusals to act) "involved in the administration of any law by the Commissioner." 21 C.F.R. § 10.3(a) (emphasis added); see also 21 C.F.R. § 10.35(b) (petition for stay must list as the decision involved "the specific administrative action being taken by the Commissioner for which a stay is requested") (emphasis added). Pharmanex seeks a stay of the September 30, 1997, letter sent to you by Ilisa Bernstein of FDA. Petition at 1. That letter, however, discusses tentative positions regarding the regulatory status of Cholestin; the letter does not describe any final administrative action taken by the Commissioner. There is, therefore, no agency action to stay.

You also request that "the agency . . . issue a stay of any form of enforcement, including public statements adverse to Pharmanex or Cholestin." Petition at 5. The agency is not acting on this request because "enforcement action[s are] solely within the discretion of the Commissioner and [are] not subject to petitions or other action by interested persons outside the agency." 40 Fed. Reg. at 40683; see Ewing v. Mytinger and Casselberry, 339 U.S. 594, 600 (1950).

The September 30, 1997, letter suggested that this matter could be resolved by an agency response to a citizen petition. You have not submitted a citizen petition, but you have submitted new data and raised new legal issues not previously submitted to FDA. Under these circumstances, FDA believes that the quickest and most appropriate route under the agency's regulations to a final decision in this matter is for the Commissioner to initiate an administrative

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proceeding pursuant to 21 C.F.R. § 10.25(b) to decide the regulatory status of Cholestin. To expedite this process, FDA will maintain the materials you submitted with your Petition in the public docket already established for the Petition, and the agency may submit to the docket other materials relevant to a decision in this matter. The agency will use its best efforts to conclude the proceeding and render a final decision on Cholestin by the end of the year.

Sincerely yours,

William B. Schultz

William B. Schultz
Deputy Commissioner for Policy